

# CY 2008 Provider Profile

## South Dakota Childhood Immunization Program

This form must be completed for individual public and private facilities approved by the South Dakota Department of Health (DOH) for participation in the State Childhood Immunization Program. This document provides shipping information and is a guide for the State Immunization Program to determine the amount of vaccine to be supplied through the Program. The form may also be used to compare estimated vaccine needs with actual vaccine supply. The Immunization Program must keep this record on file with the *Provider Certification* form. *The Provider Profile* form must be updated annually or more frequently if estimates of children served changes (e.g. private provider becomes an agent of a Federally Qualified Health Center).

|                          |                        |
|--------------------------|------------------------|
| Facility / Provider Name | <b>Provider Number</b> |
|--------------------------|------------------------|

|                   |      |       |    |       |
|-------------------|------|-------|----|-------|
| Contact Person(s) | Last | First | MI | Title |
|-------------------|------|-------|----|-------|

|  |        |      |       |     |
|--|--------|------|-------|-----|
| Vaccine Delivery Address<br>(Street Address) | Street | City | State | Zip |
|--|--------|------|-------|-----|

|                                   |        |      |       |     |
|-----------------------------------|--------|------|-------|-----|
| Mailing Address<br>(if different) | Street | City | State | Zip |
|-----------------------------------|--------|------|-------|-----|

Telephone Number \_\_\_\_\_ Fax Number \_\_\_\_\_ Email \_\_\_\_\_

Special Shipping Instructions \_\_\_\_\_

A. Type of Facility (please check only one; see back for definitions)

☐ Public Health Department

☐ Private Practice

☐ Public Hospital

☐ Private Hospital

☐ Other Public

☐ Other Private

B. Is your facility a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC)?

☐ Yes

☐ No

C. For the 12-month period beginning 01/01/08, estimate the **number** of children who will receive vaccinations at your practice/clinic.

**< 1 year old**

**1-6 years**

**7-18 years**

**Total**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

D. Of the totals entered above, how many children are expected to be VFC eligible because they are:

***Do not count the same child in more than one category.***

**< 1 year old**

**1-6 years**

**7-18 years**

**Total**

Enrolled in Medicaid \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Without Health Insurance \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

American Indian/Alaskan  
Native \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Underinsured\* \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**\*Underinsured** – The patient has health insurance that does not cover vaccines.

E. **For Private Clinics only:** If your clinic works under another clinic, please give the clinic name:

\_\_\_\_\_

Signature (person filling out this form)

Date

***Definitions:***

*Public Providers:* Includes state, district, county, or city public health facilities where immunizations are administered. Also includes IHS clinics and IHS hospitals.

*Private Providers:* Individual or group private primary care or pediatric practices (includes also private practices in which some or all clients are members of managed care organizations).

**CY 2008 Provider Certification  
South Dakota Childhood Immunization Program**

Facility Name \_\_\_\_\_ Provider Number \_\_\_\_\_

*In order to participate in the State Childhood Immunization Program, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization, health department, community/migrant/rural clinic, or other entity of which I am the physician-in chief or equivalent, agree to the following:*

1. Screen patients at all immunization encounters for eligibility and administer VFC-purchased vaccine only to children who 18 years of age or younger who meet one or more of the following categories:
  - a. Is federally vaccine-eligible
    - (1) Is an American Indian or Alaska Native
    - (2) Is enrolled in Medicaid
    - (3) Has no health insurance
    - (4) Is Underinsured: Children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (VFC- eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount-- once that coverage amount is reached, these children are categorized as underinsured. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). If the vaccine has universal status then the child does not need to be referred (please see most current vaccine eligibility chart).
  - b. Is considered State vaccine-eligible under criteria determined by each grantee (e.g., underinsured children not served through a FQHC or RHC) for administration of pediatric vaccine purchased with 317 or other State funds.
2. Comply with immunization schedule, dosage, and contraindications that are established by the ACIP and included in the VFC program unless:
  - a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate
  - b. The particular requirements contradict state law, including those pertaining to religious and other exemptions
3. Maintain all records related to the VFC program for a minimum of three years and make these records available to public health officials including the state or Department of Health and Human Services (DHHS) upon request.
4. Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
5. Not charge a vaccine administration fee to the non-Medicaid VFC-eligible children that exceeds the administration fee cap of \$13.56 per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
6. Not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
7. Distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
8. Comply with the requirements for ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.
9. The grantee or the provider may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If the provider chooses to terminate the agreement, he or she agrees to properly return any unused VFC vaccine.

10. I agree to post, in a prominent clinic location, signage stating “Immunization records may now be shared without consent.
11. I will allow immunization clinic audits to be performed by the appropriate Department of Health staff. Acceptance of this requirement is acknowledgement of permission for these audits to be performed.
12. I will submit my Clinic Inventory and Doses Administered reports to the state by the 5<sup>th</sup> of each month. If I do not have the South Dakota Immunization Information System, I am required to submit a monthly Vaccine Administration Monthly Report (Form 05/2006) by the 5<sup>th</sup> of each month.
13. **CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION:** Consultant agrees that neither the Consultant, nor any of Consultant’s principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions by any Federal department or agency. Consultant will provide immediate written notice to the Department of Health, Division of Administration (600 East Capitol Avenue, Pierre, SD 57501 (605) 773-3361), if Consultant, or any of Consultant’s principals, becomes debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions involving Federal funding. Consultant further agrees that if this contract involves federal funds or federally mandated compliance, then Consultant is in compliance with all applicable regulations pursuant to Executive Order 12549, including Debarment and Suspension and Participants’ Responsibilities, 29 C.F.R. § 98.510 (1990).

### **Vaccine Management Requirements**

#### **Designate Vaccine Personnel**

- Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for some key requirements and provide oversight for all vaccine management within the office.
- The designated vaccine coordinator and backup must be responsible for the following vaccine management activities:
  - Adjusting the temperature of a vaccine storage unit
  - Documenting the temperature on the temperature logs for each storage unit
  - The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
- The primary and backup vaccine coordinators are responsible for training other staff that are responsible for administering vaccines or may be required to transport vaccine in an emergency situation based on the vaccine storage and handling plans. A simple log sheet with the staff member’s name and date of training should be kept as documentation
- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office

#### **Storage and Handling Plans**

- The routine vaccine storage and handling plan should include guidance on aspects of routine vaccine management which include:
  - ordering vaccines
  - controlling inventory
  - storing vaccines and monitoring storage conditions
  - minimizing vaccine wastage
  - vaccine shipping including receiving, packing and transporting
- The emergency vaccine storage and handling plan should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include:
  - Person(s) responsible for preparing and transportation including contact information
  - How this person will be notified that vaccine needs to be moved
  - Location that will receive vaccine
  - How receiving location will be notified of transport
  - How to pack vaccine for transport
  - Worksheet to document vaccine involved in power or equipment failure

At a minimum the emergency plan must be reviewed and updated (as necessary) on annual basis or when there is a change in staff that has responsibilities in the emergency plan.

## **Vaccine Storage Equipment**

- Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with a separate exterior door or; 2) stand-alone refrigerators and freezers. Thermometers must be certified.
  - The refrigerator(s) or freezer(s) used for vaccine storage must
    - be able to maintain required vaccine storage temperatures year-round;
    - be large enough to hold the year's largest inventory;
    - have a working thermometer certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment
    - be dedicated to the storage of vaccines (food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature)

## **Vaccine Storage Practices**

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine
- Notify the immunization program of any vaccine doses that will expire before they can be administered. Only under the approval and direct guidance of the state, and only if the cold chain can be assured, redistribute short-dated vaccines to high-volume providers who are able to administer it before it expires
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas
- Properly space stored vaccine to allow for cold air circulation around the vaccine
- Do not store vaccines in the door of the storage unit

## **Temperature Monitoring**

- Post a temperature log on the vaccine storage unit door or nearby and readily accessible
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35° – 46° F (2° – 8°C). The freezer temperature should be <5°F (<-15°C); Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges and document actions taken on the temperature log
- Maintain an ongoing file of temperature logs, and store completed logs for three years

## **Vaccine Shipments**

- Immediately check vaccine cold chain monitors<sup>1</sup> and document the temperature inside the transport unit when vaccine arrives at office or clinic
- Take proper action if cold chain monitor was activated
- Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations.

## **Vaccine Wastage**

- Notify the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines promptly after discovery of the incident. Follow the guidance of the state on how to document and report the incident.
- Implement written procedures to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain
- Keep vaccine wastage below 5%. Wastage approaching 5% may result in an unannounced clinic audit by appropriate Department of Health staff. Vaccine wastage exceeding 5% may result in the removal of the agency/provider from the South Dakota Immunization Program.
- Remove wasted/expired vaccine from viable vaccine storage to prevent inadvertent administration.

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<sup>1</sup> Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

- All providers are allowed one excused episode of vaccine wastage due to “provider negligence”. After that one time, any vaccine wastage may result in the provider being charged for the damaged vaccine. The provider will receive an invoice for the wasted vaccine. The invoice will reflect the CDC contract cost of the vaccine, minus the excise tax. Reimbursement for the cost of the vaccine wasted shall be due 30 days from the date of the invoice, and the provider will not receive any vaccine until the wastage has been resolved. Wastage reimbursement must be sent to the Immunization program and may occur through one of the following methods: A check made out to SDDOH, for the invoiced amount of wasted vaccine, **OR** A like amount of vaccine may be privately purchased to replace the wasted vaccine. Send a copy of the invoice for the purchased vaccine.
- Return, as directed by the grantee, all spoiled or expired publicly purchased vaccines for excise tax credit
  - Prior to implementation of centralized distribution, providers should return spoiled/expired vaccine to the grantee
  - Following implementation of centralized distributors, providers should return vaccine to the centralized distributor

### **Vaccine Preparation**

- It is not acceptable clinical practice to pre-draw vaccines into syringes. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

### **Vaccine Ordering and Inventory Management**

- Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of excess vaccine inventory
- Develop and maintain complete, accurate and separate stock records for both public and private vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to physically distinguish between their public and private vaccine stock.

### **Vaccine Security & Equipment Maintenance**

- Post warning notices at both the electrical outlet and at the circuit breaker to prevent power from being disconnected

\*It is now a requirement that **all practitioners** within an enrolled facility be listed on this form if they order the administration of childhood vaccines. Please list each practitioner on the lines provided. One physician is required to sign the “Provider Certification” form on behalf of all staff within the facility who are involved with immunizations.

**Please Print**

[illegible]

(Please use the reverse of this form if more space is necessary)

It is also required that **all** persons ADMINISTERING vaccines under the supervision of a prescribing VFC Provider (those enrolled above) be listed:

[illegible]

(Please use the reverse of this form if more space is necessary)



The original of this record must be submitted to and kept on file with the Immunization Program, South Dakota Department of Health, and must be updated annually in accordance with state policy.

Physician Name (printed) \_\_\_\_\_

Medical License Number \_\_\_\_\_ Medicaid Provider Number \_\_\_\_\_

Physician Signature \_\_\_\_\_

(2008)